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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,766	04/29/1999	EIJIRO WATANABE	0020-4559P	6045

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/301,766

Applicant(s)

WATANABE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 16-23 and 28-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5, 8-10, 16-23 and 28-30 is/are rejected.
7) ☒ Claim(s) 6 and 7 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response to the Remarks filed 15 November 2004, no amendments to the claims were filed.
2. The objection to the specification and the rejection under 35 U.S.C. § 112, second paragraph, are withdrawn in view of Applicant's response.
3. The rejection under 35 U.S.C. § 101 is withdrawn in view of Applicant's clarification of the evidence provided in the Watantabe Declaration filed under 37 CFR § 1.132 on 11 February 2004, page 8 of the Remarks.
4. The provisional rejection for Double Patenting over copending application 08/922,766 [sic], designated by the Examiner in error for application 08/922,914, is withdrawn because a Terminal Disclaimer was timely filed on 9 November 2000 and approved on 13 December 2000.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

6. The substitute specification filed 15 November 2004 has been approved by the Examiner and entered into the file.

Claim Rejections - 35 USC § 112

7. Claims 1-5, 8-10, 16-23 and 28-30 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

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the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 14 May 2004. Applicant's arguments filed 15 November 2004 have been fully considered but they are not persuasive.

In light of the Remarks filed 15 November 2004 concerning what is described in the Watanabe Declaration filed 11 February 2004, Applicant has described an isolated nucleic acid encoding a raffinose synthase from *Brassica juncea* having the amino acid sequence described in SEQ ID NO: 5.

The claims as directed to isolated nucleic acids encoding SEQ ID NOs 1 or 7 lack adequate written description.

The Examiner notes that SEQ ID NOs 1 and 7 appear to be incomplete amino acid sequences and thus clearly lack adequate written description support in the specification. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein,

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and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined.

For claims directed to isolated nucleic acids encoding the amino acid sequence of SEQ ID NO: 3, Applicant has failed to adequately describe such sequences because Applicant has failed to adequately establish a structural-functional relationship. See MPEP § 2163 which states that the claimed invention as a whole may not be

adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

For claims directed to isolated nucleic acids having a nucleotide sequence obtained by PCR amplification from other plants and that hybridizes to an exemplified nucleic acid, Applicant fails to adequately describe such a genus of isolated nucleic acids encoding raffinose synthase. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA

encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. In the instant case Applicant does not describe structural features common to the member of the genus as broadly claimed.

Applicant argues that the discrepancy in the degree of "homology" in the data set provided by the Applicant and by the Examiner is due to differences in the computer program used to analyze the data (page 5, 2nd paragraph of the Remarks). This argument is not found to be persuasive because Applicant has failed to adequately describe a structural-functional relationship between the genus of isolated nucleic acids encoding raffinose synthase as broadly claimed.

Applicant argues that BLAST is a local alignment program, and does not make global alignments between sequences to calculate total percent homologies (page 6, 2nd paragraph of the Remarks). This argument is not found to be persuasive for the reasons put forth in the previous Office action. Given the evolutionary relationship between raffinose synthase and stachyose synthase, even a local alignment would not adequately distinguish the two simply based on amino acid sequence because both enzymes would have similar binding regions, and distinguishing characteristics are not described in the instant specification.

Applicant argues that the identities between RFSS and STSs are about 40%, and that the identities between RFSS and STSS range from 40% to about 50, the identities among RFSSs are 60% or more and that the identities among STSs are also 60% or more. That the identities among RFSSs or the identities among STSs are higher than the identities between RFSSs and SIPs or the identities between RFSSs and STSs, thus, based on the results of analyses by BLAST program, RFSSs, SIPs or STSs can be distinguished (page 7, 2nd paragraph of the Remarks). This argument is not found to be persuasive for the reasons of record.

Applicants argue that the evidence of record firmly establishes 1) that raffinose synthase genes as a genus are more closely related to each other than to stachyose synthase genes or imbibition protein genes suggested by the Examiner, and therefore the skilled artisan can distinguish a raffinose synthase gene from either of a stachyose synthase gene or an homology analysis and 2) that a imbibition protein gene by proper gene identified as a raffinose synthase gene by homology analysis is most likely to actually have the biochemical activity a raffinose synthase gene (page 9, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reasons given supra.

8. Claims 1-5, 8-10, 16-23 and 28-30 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 5, plants transformed therewith and methods of using such isolated nucleic acid, does not reasonably provide enablement for other isolated nucleic acids encoding raffinose synthase. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is modified from that of record as set forth in the last Office action mailed 14 May 2004 in view of Applicant's response. Applicant's arguments filed 15 November 2004 have been fully considered but they are not persuasive.

In light of the Remarks filed 15 November 2004 concerning what is taught in the Watanabe Declaration filed 11 February 2004, Applicant has taught an isolated nucleic acid encoding a raffinose synthase from *Brassica juncea* having the amino acid sequence described in SEQ ID NO: 5.

Applicant has not taught how to make and use other isolated nucleic acids encoding raffinose synthase as broadly claimed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has only taught how to make and use an isolated nucleic acid encoding a raffinose synthase having the amino acid sequence of SEQ ID NO: 5. The teachings of the art as to the relative skill of those in the art to distinguish the function of a protein having raffinose synthase simply based of amino acid sequence similarity can be found

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in previous Office actions. The art teaches that ultimately the function of any DNA sequence, whose identity is based solely on homology, can only be proven by experiments designed to evaluate that function (Duggleby 1997, Gene 190:245-249, see page 248, left column, last paragraph, cited in a previous Office action). Hence, given the breadth of the claims, the amount of guidance provided by Applicant on how to make and use other raffinose synthase encoding nucleic acids, the state of the art at the time of Applicant's invention and the relative skill of those in the art at the time of the invention, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use the invention as broadly claimed.

Allowable Subject Matter

9. Claims 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

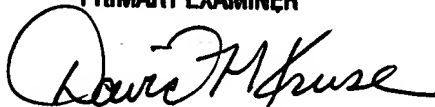
11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written over a circular stamp or mark.

David H. Kruse, Ph.D.
18 February 2005

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13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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